

Remarks

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

Claims 5, 13, 22 and 32 have been amended, and claim 44 has been added.

Claims 4, 6-9, 20, 24-31, 34, 37, 38 and 43 have been withdrawn from consideration. Consequently, claims 1-3, 5, 10-19, 21-23, 32, 33, 35, 36, 39-42 and 44 are currently pending and under consideration.

Proposed drawing amendments are submitted with this amendment under a separate cover letter. In FIG. 1A, the section line "A-A" has been changes to "I-I" in order to obviate the objection in the Notice of Draftsperson's Patent Drawing Review. These drawing amendments are editorial in nature and do not add new matter to the application.

On page 2, the Office Action required that the election of Species 1 be confirmed in writing. To reiterate the previous oral election, the Applicants hereby elect Species 1 for prosecution without traversal. Claims 1-3, 5, 10-19, 21-23, 32, 33, 35, 36, 39-42 and 44 read on the elected species, and claims 4, 6-9, 20, 24-31, 34, 37, 38 and 43 have been withdrawn from consideration. As acknowledged on page 3 of the Office Action, independent claim 1 is currently generic as to all of the species.

The Applicants acknowledge with appreciation that on page 7 of the Office Action it was indicated that claims 5, 13 and 14 contained allowable subject matter.

As a result, claims 5 and 13 have been rewritten into independent form. Consequently it is submitted that claim 5, 13 and 14 are in condition for allowance.

On page 4, the Abstract was objected to due to a number of informalities. These informalities have been corrected in the present response. The specification has also been amended to bring it into conformance with the amendment to FIG. 1A in the drawings and has been amended to correct some typographical errors.

Further, on page 4 of the Office Action, independent claim 1 was "rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. (US 6,048,352)." It is well settled law that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference in as complete detail as is contained in the claim. In traversal, the Applicants submit that the Douglas patent does not disclose the invention set forth in the claims.

For example, the Douglas patent fails to disclose "a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body" and "wherein said capillary channel is dimensioned to draw a body fluid into said annular space through capillary action." It was argued on pages 4-5 of the Office Action that in the Douglas patent "[b]ecause of the small annular space between the lancet and the main body, body fluid is inherently drawn into the annular space through capillary action." However, there is no inherent disclosure of such a feature. For an element to be inherently disclosed, it must "necessarily be present in the thing described in the reference." In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir.

1999) (citing Continental Can Co. v. Monsanto Co., 948 F2d 1264, 1268 (Fed. Cir. 1991)), See also, MPEP §2112, Schering Corp. v. Geneva Pharmaceuticals, Inc., No. 02-1540 (Fed. Cir. August 1, 2003). Indeed, inherency “may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” 49 USPQ2d at 1951. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” Ex parte Levy, 17 USPQ2d 1461, 464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original).

Even assuming for arguments sake that the space between the skin-lancing member 96 and passage 94 in the Douglas patent could be dimensioned draw fluid through capillary action, such is still not a necessary consequence of the Douglas patent. For instance, it is conceivable that the space between the skin-lancing member 96 and passage 94 in FIG. 17 of the Douglas patent could be too small so as to be incapable of drawing body fluid via capillary action. For example, blood typically is unable to flow via capillary action in passageways that are sized ten (10) microns or less. Since the Douglas patent fails to disclose the size of the space between the skin-lancing member 96 and passage 94, it is conceivable that this space is smaller than ten (10) microns such that it is unable to draw blood via capillary action. Moreover, if the space between the skin-lancing member 96 and passage 94 were sized to draw fluid via capillary action, the function of the disposable lancet 90 in the Douglas patent

would be destroyed or at least significantly hampered. As an example, since the capillary space in passage 94 would be smaller than the size of passage 92 and smaller capillaries tend draw fluid to a greater degree, the fluid would more inclined to flow into passage 94 rather than passage 92, thereby the body fluid would not be drawn onto the test strip 19 at the end of passage 92. Thus, the features recited in claim 1 are not necessarily present in the Douglas patent, and consequently, would not be inherent in the Douglas patent. For this and other reasons, it is submitted that claim 1 is not anticipated by the Douglas patent, and therefore, claim 1 and its dependent claims are allowable over the references of record.

On page 2 of the Office Action, claim 22 was rejected as being anticipated by the Douglas patent. In traversal it is submitted that the Douglas patent fails to disclose all of the features recited in claim 22. For example, the Douglas patent fails to disclose "a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body" and "wherein said capillary channel is dimensioned to draw a body fluid into said annular space through capillary action." As discussed in detail above, the Douglas patent fails to disclose, either expressly or even inherently, a capillary channel that is dimensioned to draw body fluid into an annular space through capillary action. In another example, the Douglas patent fails to disclose or suggest "a testing means for testing the body fluid drawn into said annular space" as recited in claim 22. As shown in FIG. 16 of the Douglas patent, test strip 19 is positioned at the end of passage 92 and not at passage 94. For arguments sake, even if body fluid could be drawn between passage 94 and skin-lancing member 96, the test

strip 19 in the Douglas patent is not able to test this fluid drawn between passage 94 and skin-lancing member 96. Since the Douglas patent fails to disclose every feature recited in claim 22, it fails to anticipate claim 22. For this and other reasons, it is submitted that claim 22 and its dependent claims are allowable over the references of record.

On page 2 of the Office Action, claim 32 was rejected as being anticipated by the Douglas patent. In traversal it is submitted that the Douglas patent fails to disclose all of the features recited in claim 32. For example, the Douglas patent fails to disclose "placing an apparatus having a defined capillary channel and a lancet disposed in said capillary channel that together define a capillary space adjacent tissue at a desired sample location" and "acquiring body fluid expressed from the body at the incision point into said capillary space through capillary action." As should be appreciated from the previous discussion, the Douglas patent does not expressly or inherently disclose such a technique for obtaining a fluid sample. For this and other reasons, it is submitted that claim 32 and its dependent claims are allowable over the references of record.

Further, on page 2 of the Office Action, claim 39 was rejected as being anticipated by the Douglas patent. In traversal it is submitted that the Douglas patent fails to disclose all of the features recited in claim 39. For example, the Douglas patent fails to disclose "providing a testing apparatus with a main body defining a capillary channel, and a lancet disposed within said capillary channel and defining an annular space between said lancet and said main body" and "withdrawing a body fluid

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into said annular space through capillary action" as recited in claim 39. The Douglas patent, as previously mentioned, does not inherently disclose withdrawing a body fluid into an annular space through capillary action. Rather, the Douglas patent discloses drawing fluid for testing into a second, separate passage (92). Since the Douglas patent fails to disclose all of the features recited in claim 39, the Douglas patent fails to anticipate claim 39. For this and other reasons, claim 39 and its dependent claims are in condition for allowance.

Independent claim 44 was added to provide further protection for the present application. It should be readily apparent from the discussion above that claim 44 is allowable over the references of record. For example, the Douglas patent fails to disclose or suggest "a lancet slidably received in the body to lance an incision in skin, wherein the lancet and the body define a capillary space that is sized to draw the body fluid via capillary action" and "a test means disposed in the capillary space to test the body fluid drawn by the capillary space." For this and other reasons, it is submitted that claim 44 is allowable over the references of record.

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the outstanding Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is clearly in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels

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that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the applicants' undersigned representative by telephone to resolve such issues.

Respectfully Submitted,

By



Charles P. Schmal, Reg. No. 45,082
Woodard, Emhardt, Moriarty, McNett &
Henry LLP
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456